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REVIEW

Disease-specific Quality of Life Assessment in Intermittent Claudication: Review

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Objectives: intermittent claudication (IC) is a common condition that has a major impact on the patients' quality of life (QoL). Generic QoL instruments often lack sensitivity to detect small but clinically significant variation in QoL. Disease-specific instruments may overcome this problem. This study aims to review various disease-specific QoL instruments available for use in IC and make recommendations for clinical utilization based on validity, reliability and responsiveness.

Methods: a detailed literature search and extensive bibliography review of all papers relating to disease-specific QoL and IC.

Results: several disease-specific QoL instruments are available for use in patients with IC. The most notable of these are the Claudication Scale (CLAU-S), Sickness Impact Profile – Intermittent Claudication (SIP_{IC}) and the VascuQoL. The Walking Impairment Questionnaire (WIQ) is an objective measure of the patient's walking ability and not a QoL instrument.

Conclusion: many of the questionnaires are new and have undergone only a limited validation process. More work is required in this field before any one disease-specific QoL instrument can be recommended for use in patients with IC.

Key Words: Disease-specific quality of life; Claudication; Review.

Introduction

Life comprises of two fundamental aspects quantity and quality. The significance of quality of life (QoL) is embodied by the World Health Organization (WHO) definition of health as a state a physical, social and mental well-being and not just an absence of infirmity.¹ Quality of life as an outcome measure in the management of intermittent claudication (IC) has become increasingly important because interventions for this condition aim to improve quality rather than quantity of life.

Intermittent claudication (IC) is a common condition,² which has been demonstrated to significantly impair quality of life. Claudicants are limited not only in their walking capacity and physical activity, but also demonstrate substantial impairment in other QoL domains including social functioning, emotional and mental health.^{3,4} Conservative management, exercise therapy, interventional radiology and surgery have all been used in the treatment of IC with the primary aim of reversing this QoL impairment.

Traditional clinical outcome measures including subjective and objective walking distances, ankle pressure measurements and blood flow characteristics have been used to evaluate the efficacy of these treatments. These clinical outcomes, however have demonstrated poor correlation with QoL measures.^{5,6} Since improving QoL is the main aim of treatment, most present day clinical trials include some form of QoL measure in their outcomes. Thus QoL as an outcome is clearly important, however, the most appropriate method of QoL analysis is disputed.

Quality of life may be analyzed using generic or disease-specific instruments. All QoL instruments, prior to use in clinical practice should have acceptable evidence of validity, reliability and sensitivity to change. Generic instruments typically analyze global QoL dimensions, e.g., physical, social and psychological well being or health. The main advantages of generic QoL instruments are their availability, suitability for use with any population or disease state and their ability to provide a "holistic measure" of QoL.⁷

Certain generic instruments can provide a single global score or "health index", which can be used in quality adjusted life year (QALY) calculations for cost effectiveness/utility analysis.⁸ The disadvantage of

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generic instruments is that they may lack sensitivity or responsiveness to change. It may be argued that they do not focus on the specific effects of the disease on QoL, and thus may not detect subtle but clinically important variations.⁷ In addition, generic QoL instruments do not analyze symptoms unique to the disease in question. The medical outcomes study (MOS) 36 item short form health survey (SF-36) is the most popular generic instruments in use and has been rigorously tested for validity, reliability and responsiveness. However, when used in patients with increasing lower limb ischaemia, no significant changes were evident in the dimensions of emotional role, mental health and social functioning.⁹ There was no significant difference in these dimensions between mild claudicants and age-matched controls.

Disease specific instruments analyze QoL related to a specific disease or a group of similar disorders. They specifically focus on the QoL domains affected by the symptoms of the disease in question, and thus theoretically are more responsive.^{7,8} This responsiveness may be positive (for example, improvement with treatment) or negative (deterioration). Disease-specific quality of life instruments, thus potentially represent an attractive alternative/accompaniment to generic QoL analysis. This review will analyze the various disease-specific instruments currently available for use in IC and make recommendations regarding the most appropriate instrument for clinical utilization.

Disease-specific Instruments

Claudication Scale (CLAU-S)

The Claudication Scale (CLAU-S) is probably the most extensively researched disease specific QoL questionnaire for IC. Developed in Germany in 1995,¹⁰ to measure the effect of Naftidrofuryl (a 5HT₂ receptor antagonist) on claudicants' QoL, the original

questionnaire consisted of 80 items in nine domains. Several items were specifically included to cover possible adverse effects of the drug. An initial validation study undertaken in 100 German patients demonstrated superior reliability and sensitivity compared with Nottingham Health Profile (NHP) a generic QoL instrument.¹¹ Initial drawbacks to the scale were managed by transforming the scoring method so that for all domains, 0 represented the worst and 100 the best possible QoL. Also the last 4 domains – depression, fatigue, vitality and anger – were aggregated into one domain termed “mood”.¹² This transformed 6-domain scale was administered to 1173 German patients with stage II claudication as part of an open post-marketing surveillance study of Naftidrofuryl.¹³ The scale was subsequently translated into French, English and Flemish using the classical and well-accepted forward-backward methodology¹⁴ and used in clinical studies in France, Germany and Belgium. This experience prompted further changes in the scale. The number items was reduced to 47 and grouped into five domains: daily living, pain, social life, disease-specific anxiety and mood. Several items relating specifically to adverse effects of Naftidrofuryl (e.g., sexual life items) were excluded. This shortened questionnaire was found to be acceptable to patients, took 10 min to complete and a score per domain was calculated as the mean of the completed items of the domain.¹⁵

International validation of CLAU-S was carried out in 480 patients in France, Belgium, Germany and U.K. from 1994–1996. This showed the scale to be valid, reliable and able to discriminate between patients with different disease states. In particular, the domains of pain and daily living were most discriminative and also correlated with the physician's assessment of change in the patient's condition.¹⁶ Further, clinical and biological variables directly or indirectly influenced the various domains, such that this functional

Table 1. Disease-specific quality of life questionnaires for intermittent claudication.

Questionnaire	Abbreviation	Language	Domains	Items	Best score	Worst score
Claudication Scale	CLAU-S	English + other	5	47	100	0
Walking Impairment Questionnaire	WIQ	English (American) +	4	16	100	0
Sickness Impact Profile – Intermittent Claudication	SIPIC	English + other	1	1	0	12
King's College Hospital's Vascular Quality of Life Questionnaire	VascuQoL	English + other	5	25	7	1
Artemis Questionnaire	ARTEMIS	French	15	64	100	0
Peripheral Arterial Occlusive Disease 86 Questionnaire	PAVK-86	German	7	86	1	4
Charring Cross Claudication Questionnaire	–	English	1	16	0	5

impairment had an impact on the general quality of life. This comprehensive validation procedure has also shown that the English, French, German, Belgian and Dutch translations are culturally and psychometrically equivalent.¹⁵ Responsiveness was tested by using the scale in a double-blind placebo controlled study to determine the effect of naftidrofuryl on QoL in claudicants.¹⁷ The pooled analysis of three studies undertaken in Germany, France and Belgium included 754 patients randomised to naftidrofuryl ($n = 382$) or placebo ($n = 372$). The QoL as measured by the CLAU-S was the primary outcome measure, with claudication distance as a secondary measure of efficacy. The baseline CLAU-S scores for each of the five domains were very similar in the two groups. With treatment the significant increase in claudication distance was accompanied by a significant increase in QoL scores in all domains except disease-specific anxiety.¹⁸

It is clear that extensive research has been performed in the derivation and validation of the CLAU-S. It is, however, inextricably linked to the drug naftidrofuryl. This does not necessarily dilute its status, though its use in more varied clinical trials, perhaps involving angioplasty or exercise would support its position as an internationally acceptable disease-specific QoL instrument for claudication.

Walking Impairment Questionnaire (WIQ)

The WIQ is among the best known of the disease-specific questionnaires in claudication. However, it was designed to objectively measure the walking ability of patients with peripheral arterial disease in the community and not specifically the impact of claudication on QoL. It has been shown that both patients and professionals estimate walking distances inaccurately.¹⁹ There is often little correlation between patient reported walking distances and the actual distance walked by the patient.²⁰

The WIQ was developed in Colorado, U.S.A. in 1990 and contains four questions. The first question has two sections: section A specific for buttock or calf claudication and section B used to evaluate other symptoms that may limit walking ability. The second question derives the WIQ distance score. This is calculated from patients' difficulty ratings for seven different walking distances (ranging from inside the home to five blocks). The third question derives the WIQ speed score and is calculated from a four-item scale of walking speed over one block. The fourth question derives the WIQ stair climbing score calculated from a three-item scale of difficulty of climbing one to three flights of stairs.²¹

In the original study, the WIQ distance and speed scores were shown to correlate with treadmill walking time in 26 claudicants without exercise-limiting co morbid diseases (e.g. angina, heart failure and chronic obstructive pulmonary disease). More recently, the WIQ distance and speed scores have been validated in a larger ($n = 145$) more heterogeneous group of claudicants and also in general medical patients without claudication ($n = 65$). The study also demonstrated a high rank-order correlation between WIQ distance and speed scores and the actual distance walked by the patients on supervised six-minute walks and four-minute walking velocity tests.²² Correlation between the WIQ and ankle-brachial index (ABI) has also been confirmed, such that on an average a 0.3 improvement in ABI is associated with a 10.3% increase in WIQ distance score.²³

Since the WIQ attempts to differentiate claudication symptoms from other leg symptoms that limit walking, it has been extensively used along with other diagnostic claudication questionnaires like the modified WHO-Edinburgh questionnaire to detect the prevalence of claudication in the community.^{24,25} Peripheral arterial disease is under reported and the WIQ has been used to recognize its widespread existence and also to group patients into claudication and non-claudication symptoms.²⁶ The WIQ has been used to objectively measure the effect of pharmacotherapy and exercise rehabilitation programmes on walking distances in patients with IC.²⁷⁻³⁰ It is widely used in the U.S.A. because it can yield a numerical answer to the question most commonly asked to claudicants – how far can you walk? However, the idea of distance in terms of blocks is essentially an American concept and may not have universal application. Although the WIQ has been validated to correlate with objective measures of walking in terms of defined distances and speed, because it does not specifically address the effect of claudication on the patient's QoL, it is not a QoL measure and therefore should not be used for this purpose.

Sickness Impact Profile – Intermittent Claudication (SIP_{IC})

The Sickness Impact Profile (SIP) is a generic QoL questionnaire developed in U.S.A. in the late 1970s. It is based on sickness-related behavior and is sensitive and culturally unbiased.³¹ It contains 136 items describing limitations in 12 well-defined categories of everyday life activity.^{32,33} Three of these categories – ambulation, body care and movement and mobility – form a physical domain. Emotional behavior, social interaction, alertness behavior and communication are aggregated into a psychosocial domain. The five

remaining categories – eating, work, sleep and rest, home management and recreations and pastimes are free standing. Overall, category and domain scores may be calculated.³³ This SIP generic questionnaire has been used to describe QoL impairment in a variety of clinical pain-related conditions such as coronary heart disease, cancer, rheumatoid arthritis and low back pain.

This SIP technique has been used to assess levels of claudication-specific dysfunction. Twelve of the 136 items in the SIP questionnaire were taken to produce an intermittent claudication (IC) specific scale called Sickness Impact Profile – Intermittent Claudication (SIP_{IC}). The 12 items in the SIP_{IC} are extracted from the SIP categories of ambulation, home management, social interaction, mobility, alertness behavior and sleep and rest. Scores represent the sum of the number of dysfunction items endorsed and range from 0–12 (0 being the best and 12 the worst QoL).³⁴ The SIP_{IC} is quick and easy to use, but the process used to extract these items and produce this simple disease-specific instrument is not clear. Similar modifications have been made to the SIP to produce shorter instruments to assess QoL impairment in head injury, low back pain, stroke (SA-SIP30) and other conditions.^{35–37}

The SIP_{IC}, the generic SIP and the SIP “ambulation” category have been tested in 148 claudicants. A significant reduction in all three scores was demonstrated in claudicants with a walking capacity of less than 70 W (W being a measure of work and not distance).³⁴ More recently the 12 item claudication specific SIP_{IC} was used along with other generic and disease-specific questionnaires in a randomised controlled trial of 253 Swedish patients with claudication to test the efficacy of invasive therapy, exercise or simple observation.³⁸ Although in both the above studies the SIP_{IC} and the whole SIP were administered together, the scores for a part of the whole questionnaire should not be analyzed independent of the overall score.³⁹ To use parts of larger generic questionnaire as a disease-specific measure requires independent validation.

King's College Hospital's Vascular Quality of Life Questionnaire (VascuQoL)

The VascuQoL is a disease specific QoL questionnaire developed at the Vascular Surgical Unit of King's College Hospital, London in 2000. The previously described disease-specific measures were all designed for claudication and did not encompass critical lower limb ischaemia. The VascuQoL was developed as a disease-specific evaluative instrument across the

whole spectrum of chronic lower limb ischaemia, which was responsive to within-patient change.

The questionnaire contains 25 items (questions) subdivided into five domains: pain (four items), symptoms (four items), activities (eight items), social (two items), and emotional (seven items). Each question has a seven-point response option. The responses are simply averaged to give an overall and a domain score ranging from 1 to 7 (1 is worst possible quality of life and 7 is best possible quality of life).⁴⁰

The questionnaire was developed in two stages according to recommended methodology.⁴¹ In stage one, a handful of “expert patients” and professionals were used in item selection. One hundred thirty-seven patients were then involved in item reduction based on the item's frequency of being most troublesome to the patient, called the “clinical impact factor”. The questionnaire thus formulated was pretested in 10 patients. In stage two, the validity, reliability and responsiveness of the questionnaire was tested in 39 patients during two attendances, 4 weeks apart. Construct validity was demonstrated by correlation with Fontaine classification of disease severity, treadmill walking distances and like domains in the SF-36. The questionnaire had a test-retest reliability of r more than 0.90. Responsiveness was assessed by correlating change in the questionnaire's total score and change in the clinical indicators of lower limb ischaemia. A similar method has been used to develop other disease-specific quality of life questionnaires.

The VascuQoL claims to be a more general disease specific questionnaire for the entire spectrum of lower limb ischaemia, rather than just for claudication. Although developed using a rigorous staged procedure, it is still relatively new. It has been validated in a relatively small number of patients and further evaluation is ongoing in a multicentre trial of bypass surgery versus angioplasty in patients with critical limb ischaemia.⁴²

The ARTEMIS scale

The ARTEMIS scale is a French questionnaire developed in 1993 specifically for use in patients with peripheral arterial occlusive disease. It is a self-administered questionnaire and combines a general (SF-36) and a specific instrument. It contains 64 items covering the 8 dimensions of the SF-36, 5 disease-specific dimensions and two differential dimensions (perception of health status evolution and perception of the future). It has been validated in 177 patients with Fontaine stage II intermittent claudication and the results reveal that patients walking greater than

500 m had significantly higher scores (better QoL) than patients walking less than 500 m.⁴³ Shortened and complete versions of the questionnaire are available in French. The ARTEMIS questionnaire was used in a large multicentre study of claudicants treated with ifenprodil tartarate 20 mg, three times daily.

More than 4000 questionnaires were analysed over 12 months with good responsiveness of the questionnaire with global clinical improvement.⁴⁴ However, the ARTEMIS scale was developed in French and has not been translated into other languages so far.

The Peripheral Arterial Occlusive Disease 86 Questionnaire (PAVK-86)

The PAVK-86 is a disease specific QoL questionnaire developed in Germany in mid 1990. It comprises of 86 individual items assigned to 7 QoL domains: functional status, pain, general complaints, mood, anxiety, social life and treatment evaluation.⁴⁵ It was originally tested in 308 patients with confirmed peripheral arterial occlusive disease (PAOD); Fontaine stages I to IV and was found to be valid, reliable and sensitive. The results showed that compared to a normal population, patients with PAOD had considerably impaired QoL, and this impairment was significantly greater in patients with Fontaine stages III and IV disease. However, no differences in QoL were found between Fontaine stages III and IV.⁴⁶ This finding may be real, but may represent lack of sensitivity. In another study involving 150 patients with stable intermittent claudication, the maximum walking distance was found to be the greatest predictor of scores in the pain, general complaints and functional status domains of the PAVK-86.⁴⁷ The PAVK-86 along with the SF-36 was completed by 104 patients before and after 4 weeks treatment with a daily intravenous infusion of 60 mg of PGE1 (Prostavasin) and at the end of 3 months. The significant increase in pain-free and maximum walking distances at the end of treatment was accompanied by significant improvement in all domains of PAVK-86 measured QoL, which was maintained at 3 months.⁴⁸ Similarly, a 12-week supervised training programme significantly increased walking distances in 31 stage II claudicants with a similar improvement in most of the QoL dimensions measured by the PAVK-86.⁴⁹ However, this QoL questionnaire is only available in German and has not yet been translated into other languages.

The Charing Cross Claudication Questionnaire

The Charing Cross Claudication Questionnaire is a 16-item symptom specific questionnaire for claudication,

which was developed at the Charing Cross Hospital in London using recommended methodology. Patients and experts produced a pool of statements used to itemize a self-administered symptom specific questionnaire, which was piloted in 20 patients. It was validated in 124 stable claudicants and was found to correlate with all the components of the WIQ and the EuroQoL, but not with ankle brachial pressure index (ABPI) or treadmill walking distances.⁵⁰ More recently, this symptom specific questionnaire was completed by 57 claudicants randomised to either a once weekly-supervised exercise motivation class or exercise advice alone.⁵¹ There was a significant fall in the SSQ score (better QoL) in the supervised class group compared to the advice alone group. However, it is still a questionnaire in its infancy and its proof of validity is more indirect through the WIQ. Moreover, it is yet to be published in peer reviewed journals.

Conclusions

The assessment of QoL in the management of patients with IC is crucially important. Generic measures lack the sensitivity to detect subtle but clinically significant differences. Disease-specific instruments potentially have an important role to play and complement the generic QoL instruments. The SF-36 has become the established generic QoL instrument in patients with vascular disease. However, there is no such clear leader among the disease-specific QoL instruments for IC. Many of the disease-specific instruments described are reasonably new and have undergone only a limited validation process.

Although none can be recommended as the gold standard, the CLAU-S seems to have emerged as perhaps the best option presently available. It has been thoroughly validated and used in several trials and the shortened version is translated for use in several languages. However, further work regarding its responsiveness and superiority over generic instruments is required. Rather than devising alternative disease-specific QoL questionnaires for IC, work should concentrate on strengthening and evaluating the existing instruments. The ultimate goal should be to establish a disease-specific IC QoL instrument that is valid, reliable and responsive and has demonstrable benefits over generic instruments.

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